

REMARKS

I. Status of Claims and Amendments

Claims 38-42, 48, and 53-67 are pending, with claims 38, 39, and 53 being independent. Claims 38-42, 48, 53, 55-59, and 61-66 have been amended without prejudice to pursuing canceled subject matter in a continuation application, and without disclaiming any subject matter. Claim 53 now depends from claim 39; claim 65 now depends from claim 38; and claim 66 now depends from claim 39. New claim 67 depends from claim 39, and find support among other places in the specification at page 2, lines 6-12.

All of the amended claims have been altered to recite "A method of treating seborrheic dermatitis in a human patient in need thereof." This language finds support throughout the application and claims as originally filed, and in the specification at page 2, line 25, to page 3, line 20, and on page 12, lines 11-14, among other places.

Claim 38 has been amended to recite "a sole active component consisting of at least one 1-hydroxy-2-pyridone," and therefore exclude other active components. Support for this language appears throughout the application, and in the specification at page 1, lines 34-37, and on page 2, lines 6-12.

Claims 40, 41, 55, 56, 61, and 62 have been amended to replace "comprises" with "has." No change in the scope of those claims is intended. Also, claims 57, 58, 63, and 64 have been amended to delete "pharmaceutical" to maintain proper antecedent basis. Finally, claim 42 has been amended to reflect the "sole active component" language of claim 38 from which it depends.

II. Patentability of the Pending Claims in Light of the Board's Decisions

Applicants respectfully submit that the amended claims are patentable in view of the decisions of the Board of Patent Appeals and Interferences for this case. In the Decision on Appeal dated September 15, 2004, the Board vacated all rejections and applied new grounds of rejection against the appealed claims. In the Decision on Request for Rehearing dated December 22, 2004, the Board clarified its earlier Decision. Below, Applicants address the main points of the Board's Decisions, and explain how the amended claims set forth above are patentable in light of those Decisions.

The Board construed the preamble of the appealed claims to read on the treatment of symptoms. Decision on Appeal at 5-6. "A method of treating a human or animal patient in need of treatment for seborrheic dermatitis," according to the Board, reasonably reads on treating such a patient for dandruff, for example. *Id.* at 5. That is because dandruff, according to the Board, may be a symptom of seborrheic dermatitis.¹ *Id.* at 6. Therefore, the Board found the appealed claims were anticipated by or obvious over prior art treatments for dandruff and other symptoms of seborrheic dermatitis. *Id.* at 7-14.

In its Decision on Request for Rehearing, the Board distinguished the *Jansen* decision cited by Applicants because (1) the procedural posture of *Jansen* invited a different mode of claim construction, (2) the absence from the present record of a

¹ Applicants note that dandruff is a disorder different from seborrheic dermatitis. See specification at 1, II. 3-7.

prosecution history similar to that in *Jansen* giving rise to a narrow claim construction, and (3) the inclusion of animals in Applicants' claimed methods. Decision on Request for Rehearing at 5 (referring to *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 68 U.S.P.Q.2d (BNA) 1154 (Fed. Cir. 2003)). Also, the Board found no intent to cure seborrheic dermatitis in Applicants' claims. *Id.* at 6. Further, the Board held that Applicants had not made clear what basic and novel properties of their claimed invention are required by the "consisting essentially of" claim language. *Id.* at 8. Finally, the Board asserted that Applicants did not address a few of its factual findings. *Id.*

A. The Claims Recite Methods for Treating Seborrheic Dermatitis

To address the Board's concerns, Applicants have amended their claims' preambles to make clear the claimed methods treat seborrheic dermatitis, not the symptoms of seborrheic dermatitis. Applicants' preambles now recite: "A method of treating seborrheic dermatitis in a human patient in need thereof." Significantly, the Federal Circuit has held that similar language distinguishes the treatment of a disease from the treatment of mere symptoms of that disease.

Even though the Board distinguished the facts of *Jansen*, the Federal Circuit's claim construction as a matter of law illuminates Applicants' new claim language. *Jansen*'s preamble recited: "A *method of treating* or preventing macrocyclic megaloblastic anemia *in humans . . .* which comprises *administering* a daily oral dosage of a vitamin preparation *to a human in need thereof . . .*" *Jansen*, 342 F.3d at 1330, 68 U.S.P.Q.2d at 1155 (emphasis added). Similarly, Applicants' claims now recite, "A

method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition" Claim 38 (emphasis added). The Federal Circuit held that the claim language at issue in *Jansen* must be interpreted to read on the treatment of a disease, not on treatment of mere symptoms. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58.

To enforce the idea that treating symptoms does not equate to treating diseases, the *Jansen* panel pointed to a similar case, *Rapoport v. Dement*, 254 F.3d 1053, 59 U.S.P.Q.2d (BNA) 1215 (Fed. Cir. 2001):

On appeal [in *Rapoport*] we gave weight to the ordinary meaning of the preamble phrase "for treatment of sleep apneas," interpreting it to refer to sleep apnea, *per se*, not just "symptoms associated with sleep apnea." *Rapoport* argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. We rejected that argument, stating, "There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition*." Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

Jansen, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (quoting *Rapoport*, 254 F.3d at 1059 and 1061, 59 U.S.P.Q.2d at 1219 and 1221, and adding emphasis). As in *Jansen* and *Rapoport*, the amended claims recite "in need thereof," indicating treatment of seborrheic dermatitis itself. Also, as in *Jansen* and *Rapoport*, the amended claims do not explicitly recite "intent," but the preambles of the claims of *Jansen*, *Rapoport*, and the present application were or ought to be interpreted to exclude prior art that fails to reveal any intent to treat the underlying conditions. Accordingly, the amended claims

should be construed to require treatment of a human patient for the disease of seborrheic dermatitis, and not just a symptom associated with the disease.

Significantly, and contrary to the Board's reasoning, the twenty years of prosecution history in *Jansen* is less relevant than the claim language itself, because similar words have similar meanings. "Just as in *Rapoport*, it is natural to interpret the nearly parallel language in the '083 patent claims in the same way." *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1158. Applicants have now amended their claims to recite preambles "nearly parallel" to those in *Jansen* and *Rapoport*. As in *Jansen* and *Rapoport*, Applicants' new claims should be construed to read on the treatment of the disease seborrheic dermatitis and not on the treatment of mere symptoms.

Under such a construction, Applicants maintain that their claimed invention is not anticipated nor obvious in view of the cited documents, because there is no disclosure in the documents cited by the Board in its Decisions that compositions described in the amended claims are administered to patients suffering from seborrheic dermatitis with the intent to treat the underlying condition. See *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58. In *Rapoport*, the claims reciting methods of treating sleep apneas could not be invalidated by prior art that taught treatment of *symptoms* of sleep apnea. See *Rapoport*, 254 F.3d at 1060-63, 59 U.S.P.Q.2d at 1221-22; see also *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58.

The Board also noted that the appealed claims recited animal patients, distinguishing the appealed claims from those at issue in *Jansen*. Decision on Request for Rehearing at 4-5. Accordingly, without prejudice or disclaimer and solely to advance prosecution, Applicants have canceled animal patients from their claims.

The Board understood Applicants' arguments to require an intent to *cure* seborrheic dermatitis. Decision on Request for Rehearing at 5. That understanding misconstrues Applicants' arguments. In the two cases cited by Applicants, the claims did not mention a cure, but the Federal Circuit interpreted the claims to exclude prior art that failed to teach an intent to cure. See *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58; *Rapoport*, 254 F.3d at 1060-63, 59 U.S.P.Q.2d at 1221-22.

The Board noted findings that Applicants allegedly failed to address. See Decision on Request for Rehearing at 8. However, Applicants saw no need to address those findings, at least for the following reasons. Regarding the scope of the claim term "seborrheic dermatitis," the Board acknowledged that Applicants' specification defined the term for the purpose of construing the appealed claims.

We are mindful that applicants' specification defines seborrheic dermatitis as follows. "Seborrheic dermatitis is understood as meaning a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites."

Decision on Appeal at 5 (quoting specification at 1, II. 3-7). That the alleged prior art may define the disease differently does not control. "During patent examination, the pending claims must be "given their broadest reasonable interpretation *consistent with the specification.*" M.P.E.P. § 2111 (*citing In re Hyatt*, 211 F.3d 1367, 1372, 54 U.S.P.Q.2d (BNA) 1664, 1667 (Fed. Cir. 2000)) (emphasis added).

Moreover, evaluating the statement "many cases of seborrheic dermatitis will respond to the same non-prescription drug regimen used to treat dandruff" depends on the definition of "seborrheic dermatitis." If seborrheic dermatitis can be equated with dandruff, then it is logical that such cases of seborrheic dermatitis will respond to

dandruff treatments. See Decision on Request for Rehearing at 8. But Applicants do not equate the claim term “seborrheic dermatitis” with dandruff. As acknowledged by the Board, Applicants define seborrheic dermatitis “as meaning a disorder of the scalp that differs from simple dandruff.” Decision on Appeal at 5. Accordingly, that cases of “seborrheic dermatitis,” as that term is used in the documents cited by the Board, might respond to dandruff treatments is not relevant to Applicants’ claims. Such disclosure renders such treatments obvious to try at best.

B. The Board’s Rejections Should be Withdrawn as Moot

1. Rejections over *Saint-Leger*

Claim 39 has been rejected under 35 U.S.C. § 102 as anticipated by *Saint-Leger*. (U.S. Pat. No. 5,650,145). Decision on Appeal at 5. Claims 38-42 and 48 have been rejected under 35 U.S.C. § 102 as anticipated by, or in the alternative, under 35 U.S.C. § 103 as unpatentable over *Saint-Leger*. *Id.* at 9. Applicants respectfully disagree with these rejections.

Applicants respectfully contend that *Saint-Leger* does not describe, teach, or suggest a method of treating seborrheic dermatitis. *Saint-Leger* recites “dermatological/cosmetic compositions for reducing or decelerating hair loss.” *Saint-Leger*, at Abstract. The examples and claims disclose uses that come no closer to the claimed invention than treating mere symptoms of, in some cases, seborrheic dermatitis. The Board agrees: “Therefore, *Saint-Leger* is directed to a method for treating a human patient with at least one symptom of seborrheic dermatitis.” Decision on Appeal at 8. As in *Jansen* and *Rapoport* discussed above, *Saint-Leger* cannot

anticipate nor render obvious methods of treating seborrheic dermatitis, because the treatment of a symptom does not render obvious a treatment of the disease.

Furthermore, amended claim 38 recites methods for treating seborrheic dermatitis by employing a composition comprising “a sole active component consisting of at least one 1-hydroxy-2-pyridone of formula (I).” Dependent claims 40-42, 48 and 65 incorporate that element by reference. See 35 U.S.C. § 112, ¶ 4 (2000). As would be understood by the skilled artisan reading that claim language, “consisting of” excludes additional compounds regarded as having pharmaceutical activity such as those described in the specification at page 1, line 26, to page 2, line 19. In contrast, the skilled artisan would also understand that the claim language does not exclude additional ingredients such as the additives mentioned in the specification on page 7, line 36, to page 8, line 16, among other places. Accordingly, claims 38, 40-42, 48, and 65 exclude methods of treating seborrheic dermatitis employing compositions having an active component that contains additional pharmaceutical ingredients such as *Saint-Leger's* halogenated antibacterial agent.

While “consisting of” often appears in the preamble of a claim, those words may be used elsewhere in the claim to modify the scope of just one element of the claim. In the *Mannesmann* decision, the Federal Circuit explained that such words may limit only the one element with which they appear. See *Mannesmann Demag Corp. v. Engineered Metal Prods. Co., Inc.*, 793 F.2d 1279, 230 U.S.P.Q. (BNA) 45 (Fed. Cir. 1986). Considering “consisting of,” the panel held, “The district court correctly observed that the phrase ‘consisting of’ appears in clause (a), not the preamble of the claim, and

thus limits only the element set forth in clause (a)." *Mannesmann*, 793 F.2d at 1282, 230 U.S.P.Q. at 46.

Accordingly, the rejections of claims 38-42, and 48 based on *Saint-Leger* should be withdrawn.

2. Rejections over *Saint-Leger* and *Lange*

Amended claims 38-42, 48, and 53-66 have been rejected under 35 U.S.C. § 103 as allegedly being obvious in view of the combined teachings of *Saint-Leger* and *Lange* (U.S. Patent No. 5,132,107). Decision on Appeal at 12. In support of this rejection, the Board contends that *Saint-Leger* and *Lange* are drawn to methods of treating a human patient having a symptom of seborrheic dermatitis. *Id.* at 8 and 13, respectively. Applicants respectfully disagree with this new ground of rejection.

As discussed above, *Saint-Leger* teaches no more than treating a symptom of seborrheic dermatitis. Similarly, *Lange* does not teach or suggest employing 1-hydroxy-2-pyridones for the treatment of anything more than symptoms of seborrheic dermatitis. The Board agrees, stating:

Lange's invention 'relates to the control of dandruff and similar scale forming conditions of the skin of the head' (column 1, lines 13-15). Lange discloses that '[o]ne may also use piroctone olamine [OCTOPIROX] in phase II because of its anti-seborrheic effect' (column 5, lines 65-66). Thus, Lange, like *Saint-Leger*, is directed to a method for treating a human patient with a *symptom* of seborrheic dermatitis.

Decision on Appeal at 13 (emphasis added). Accordingly, *Lange* does not teach or suggest Applicants' claimed methods of treating seborrheic dermatitis *per se*, which employ 1-hydroxy-2-pyridones in compositions containing at least one surfactant and, in

various claims, a certain pH range, an active component of limited scope, keratolytic agents, and/or lactic acid, for the treatment of seborrheic dermatitis.

Therefore, the rejections of claims 38-42, 48, and 53-66 over *Saint-Leger* and *Lange* should be withdrawn as moot.

III. Evidence of Commercial Success

If the Examiner believes that a *prima facie* case of obviousness can be sustained against Applicants' amended claims, Applicants respectfully request the Examiner to consider their evidence of commercial success.

Applicants attach the Declaration of Steve Bradford of Medicis Pharmaceutical Corporation and 12-Month Rolling Prescription Report showing the market share garnered by the shampoo which among other products can be used to practice the methods claimed in this application. In December 2004, Loprox® Shampoo filled 37,000 prescriptions in the market for prescription shampoos. See Declaration of Steve Bradford at ¶ 6. Significantly, market share of Loprox® Shampoo has gained at the expense of other products, namely selenium sulfide, Capex®, and ketoconazole. See 12-Month Rolling Prescription Report. For example, from December 2003 to December 2004, new prescriptions of Loprox® Shampoo increased by 16%. *Id.* Total prescriptions of Loprox® Shampoo increased from 29,000 per month to 37,000 per month in the same period. *Id.*

Loprox® Shampoo embodies the compositions useful in the claimed methods. Loprox® Shampoo has been approved for the treatment of seborrheic dermatitis by the Food and Drug Administration. When administered to treat a patient for seborrheic

dermatitis, that use of Loprox® Shampoo "is covered by the pending claims in the above-identified patent application." Declaration of Steve Bradford at ¶ 4.

"It is the secondary considerations that are often the most probative and determinative of the ultimate conclusion of obviousness or nonobviousness." *Pro-Mold and Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2d 1626, 1630 (Fed. Cir. 1996). The increasing market share of Loprox® Shampoo, which is prescribed for the treatment of seborrheic dermatitis, firmly demonstrates the non-obviousness of the claimed invention. Accordingly, the obviousness rejections should be withdrawn.

CONCLUSION

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By:



Jeremy M. Stipkala
Reg. No. 44,359